

### **Remarks**

This is in response to the Office Action dated October 26, 2006.

The instant invention is presently used in the Portex/Wallace SurePro embryo replacement catheter. The catheter is formed of two extruded layers: the outer, thicker layer, forming the main structure of the catheter, is of a bubble-filled material with a high ultrasound reflectivity; the inner layer does not have any bubbles and is much thinner. The purpose of the inner layer is to provide a smooth inner passage to the catheter so as to make it as atraumatic as possible for embryos. Without this inner layer, the inner surface would be interrupted by the occasional bubble where it breaks the surface, so it would not be as smooth.

Per the above amendments, the independent claims have been amended to specify that the bubble-filled layer is the thicker layer of the catheter. The amendments also serve to clarify that the gas bubbles are formed within the actual plastics material forming a layer of the device.

The examiner has relied upon William (US 5211627) for anticipatorily rejecting claims 1-4, 7-8, 13-14 and 16-17, and the combination of William with Tickner (US 4265251) for rejecting as obvious claims 9-11.

The examiner moreover has rejected all of the claims relying on the combination of a number of references: Bosely (US 5201314), Jones (US 6506516) and Rammler (US 5327891), and possibly in combination with either Sarkis (US 5921933) or Onwumere (US 5250649). Koulik (US 7014610) was combined with either William or the combination of just noted references for rejecting claim 12.

The main citation relied on by the Examiner – William (US5211627) - does not really describe an echogenic catheter. Instead, it describes a catheter designed to

produce an aerated liquid for supply to a body cavity. The catheter has one lumen along which the liquid is supplied and a parallel lumen along which air is supplied. The two lumens open into a short common section at the front of the catheter where the air mixes with the liquid before being ejected from the catheter. The catheter does not have any layer with bubbles unless one regards the forward section of the catheter as a layer. The amendments to the claims should now clarify the difference from the catheter described in William by making it clear that the gas bubbles of the present invention are actually dispersed within the plastics material forming a layer of the device. William does not suggest anywhere that any plastics layer of his catheter contains gas bubbles within a plastics material, as required by the amended claims of the present application.

Tickner (US4265251) similarly describes a method of injecting into a body a liquid containing bubbles. There is nothing in this document to suggest incorporating bubbles into any plastics component.

Bosely (US5201314) describes a catheter employing particles embedded within a plastics material in order to increase ultrasound reflectivity. See col. 7, lines 25-28 and particularly lines 59-60 where Bosely states that gases may be used, "so long as they form a composite with ultrasonically reflective particles in the matrix." Thus, nowhere is there any suggestion in Bosley that gas bubbles be used and, more particularly, there is no suggestion that a catheter could have one layer with bubbles and another layer without bubbles.

Jones (US6506156) describes an echogenic coating for a medical device including a plastics material with voids or microspheres. This material is coated onto an existing device so only forms a minor part of the thickness of the device, in contrast with the arrangement required by the amended claims of the present application where a medical device has two extruded plastics layers and the thicker one of these layers is provided with gas bubbles. The arrangement of the present invention is, therefore, quite different from the device of Jones in that, in the present invention it is the main

structural layer of the device that incorporates the gas bubbles, not merely an additional outer coating applied to the surface of a preformed device.

Rammler (US5327891) describes a catheter having channels along it containing microbubbles in a liquid or gel within the channel. This is quite different from the arrangement of the present invention in which bubbles are incorporated into the plastics material itself forming the structure of the device, as required by the amended claims of the present application.

Sarkis (US59219330) describes a medical device having a coating or other components of a plastics material containing nanometre-size particles. There is no suggestion in this document that gas bubbles be used in place of particles, as required by the claims of the present application. In many medical applications it is preferable to avoid including foreign materials. Incorporating particles into a medical device introduces the risk of potential incompatibility with the body and the risk that particles will become detached at the surface. Gas bubbles avoid these problems and have been found, surprisingly, to increase significantly the visibility of the catheter under ultrasound observation.

Onwumere (US5250649) describes a material suitable for forming catheters and coatings on pacemaker leads. The material may include antithrombogenic agents, antimicrobial agents and radio-opaque materials but there is no suggestion that gas bubbles be incorporated into the material and, more particularly there is no suggestion that bubbles be incorporated in a manner to increase echogenicity. Moreover, there is no suggestion that a catheter have two layers, one containing bubbles and the other not, in the manner of the present invention.

Kulak (US7014610) describes an echogenic device made from a porous material formed by extracting a phase separated composition from a polymeric material. Such a

porous device is quite different from a material containing gas bubbles of the kind of the present invention.

In light of the foregoing, it is respectfully submitted that the pending claims are patentably distinguishing over the prior art. Accordingly, the examiner is respectfully requested to reconsider the application and pass the same to issue at an early date.

Respectfully submitted,



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